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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,179	10/03/2006	Tania Maria Rodrigues	C&R-105	1198

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,179	RODRIGUES ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-66* is/are pending in the application.

4a) Of the above claim(s) *52-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-51 and 65-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 52-64 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim "shall refer to such other claims in the alternative only" and "a multiple depend claim shall not serve as a basis for any other multiple dependent claim". See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 46 and 65-66, drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12, and related molecules.

Group II, claim(s) 46, drawn to a nucleic acid comprising the sequence of SEQ ID NO:9 or 11, and related molecules.

Group III, claim(s) 46, drawn to a ligand that binds to a polypeptide of SEQ ID NO:10 or 12, which is not an antibody.

Group IV, claim(s) 46, drawn to an antibody that binds to a polypeptide of SEQ ID NO:10 or 12.

Group V, claim(s) 46, drawn to a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group VI, claim(s) 46, drawn to a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group VII, claim(s) 46, drawn to a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group VIII, claim(s) 46, drawn to a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group IX, claim(s) 46, drawn to a compound that binds to a polypeptide of SEQ ID NO:10 or 12 without inducing any of the biological effects of the polypeptide.

Group X, claims(s) 46, drawn to a kit for diagnosing disease comprising a nucleic acid probe that hybridizes to a nucleic acid of SEQ ID NO:9 or 11.

Group XI, claim(s) 46, drawn to a transgenic non-human animal.

Group XII, claim(s) 46, drawn to a knock-out non-human animal.

Group XIII, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a polypeptide of SEQ ID NO:10 or 12.

Group XIV, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a nucleic acid encoding a polypeptide of SEQ ID NO:10 or 12.

Group XV, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a ligand that binds to a polypeptide of SEQ ID NO:10 or 12, which is not an antibody.

Group XVI, claim(s) 47, drawn to a method of diagnosing a disease in a patient using an antibody that binds to a polypeptide of SEQ ID NO:10 or 12.

Group XVII, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XVIII, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XIX, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XX, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XXI, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a compound that binds to a polypeptide of SEQ ID NO:10 or 12 without inducing any of the biological effects of the polypeptide.

Group XXII, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a transgenic non-human animal.

Group XXIII, claim(s) 47, drawn to a method of diagnosing a disease in a patient using a knock-out animal.

Group XXIV, claim(s) 47-51, drawn to a method of treating a disease in a patient using a polypeptide of SEQ ID NO:10 or 12.

Group XXV, claim(s) 47-51, drawn to a method of treating a disease in a patient using a nucleic acid encoding a polypeptide of SEQ ID NO:10 or 12.

Group XXVI, claim(s) 47-51, drawn to a method of treating a disease in a patient using a ligand that binds to a polypeptide of SEQ ID NO:10 or 12, which is not an antibody.

Group XXVII, claim(s) 47-51, drawn to a method of treating a disease in a patient using an antibody that binds to a polypeptide of SEQ ID NO:10 or 12.

Group XXVIII, claim(s) 47-51, drawn to a method of treating a disease in a patient using a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XXIX, claim(s) 47-51, drawn to a method of treating a disease in a patient using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XXX, claim(s) 47-51, drawn to a method of treating a disease in a patient using a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XXXI, claim(s) 47-51, drawn to a method of treating a disease in a patient using a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:10 or 12.

Group XXXII, claim(s) 47-51, drawn to a method of treating a disease in a patient using a compound that binds to a polypeptide of SEQ ID NO:10 or 12 without inducing any of the biological effects of the polypeptide.

Group XXXIII, claim(s) 47, drawn to a method of treating a disease in a patient using transgenic non-human animal.

Group XXXIV, claim(s) 47, drawn to a method of treating a disease in a patient using a knock-out animal.

Group XXXV, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a polypeptide of SEQ ID NO:10 or 12.

Group XXXVI, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a nucleic acid encoding a polypeptide of SEQ ID NO:12 or 10.

Group XXXVII, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a ligand that binds to a polypeptide of SEQ ID NO:12 or 10, which is not an antibody.

Group XXXVIII, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using an antibody that binds to a polypeptide of SEQ ID NO:12 or 10.

Group XXXIX, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 40, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 41, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 42, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 43, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a compound that binds to a polypeptide of SEQ ID NO:12 or 10 without inducing any of the biological effects of the polypeptide.

Group 44, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using transgenic non-human animal.

Group 45, claim(s) 47, drawn to a method of monitoring the therapeutic treatment of a disease using a knock-out animal.

Group 46, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a polypeptide of SEQ ID NO:12 or 10.

Group 47, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a nucleic acid encoding a polypeptide of SEQ ID NO:12 or 10.

Group 48, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a ligand that binds to a polypeptide of SEQ ID NO:12 or 10, which is not an antibody.

Group 49, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using an antibody that binds to a polypeptide of SEQ ID NO:12 or 10.

Group 50, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 51, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 52, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 53, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 54, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a compound that binds to a polypeptide of SEQ ID NO:12 or 10 without inducing any of the biological effects of the polypeptide.

Group 55, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using transgenic non-human animal.

Group 56, claim(s) 47, drawn to a method of identification of a compound that is effective in the treatment/diagnosis of a disease using a knock-out animal.

Group 57, claim(s) 47, drawn to a method of screening candidate compounds using a polypeptide of SEQ ID NO:12 or 10.

Group 58, claim(s) 47, drawn to a method of screening candidate compounds using a nucleic acid encoding a polypeptide of SEQ ID NO:12 or 10.

Group 59, claim(s) 47, drawn to a method of screening candidate compounds using an antibody that binds to a polypeptide of SEQ ID NO:12 or 10.

Group 60, claim(s) 47, drawn to a method of screening candidate compounds using a compound that decreases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 61, claim(s) 47, drawn to a method of screening candidate compounds using a compound that increases the level of activity of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 62, claim(s) 47, drawn to a method of screening candidate compounds using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 63, claim(s) 47, drawn to a method of screening candidate compounds using a compound that decreases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 64, claim(s) 47, drawn to a method of screening candidate compounds using a compound that increases the level of expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:12 or 10.

Group 65, claim(s) 47, drawn to a method of screening candidate compounds using a compound that binds to a polypeptide of SEQ ID NO:12 or 10 without inducing any of the biological effects of the polypeptide.

Group 66, claim(s) 47, drawn to a method of screening candidate compounds using a transgenic non-human animal.

Group 67, claim(s) 47, drawn to a method of screening candidate compounds using a knock-out animal.

The inventions listed as Groups 1-66 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: the special technical feature of Group I (polypeptide of SEQ ID NO:8 or 10, or related molecules including functional equivalents) is known in the art. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature defines a contribution over the prior art. The prior art acknowledges growth hormone, which would be considered a functional equivalent to the molecule of Group I, therefore, the polypeptide of Group I cannot serve as a basis for unity of invention.

37 CFR 1.475 does not provide for the inclusion of multiple inventions. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims will be considered the mane invention (see PCT Article 17(3)(a). Accordingly, the inventions of Groups 2-66 do not have unity of invention with the composition of Group I.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant should note that due to the complexity of the restriction, if methods are elected, further restriction may be necessary. Any inconvenience this causes is regretted.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647